TEST ARTICLE NAME
PAPC II

TEST ARTICLE IDENTIFICATION
II OVA

TEST ARTICLE PHYSICAL DESCRIPTION
Polyamide, Polyolefin and Cellulose plaques

TEST ARTICLE RECEIVED
March 28, 2018

SPONSOR
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FibreTuff Medical Biopolymers
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USP Biological Reactivity Tests, In Vivo
USP Plastic Class VI

USP Systemic Toxicity Study in the Mouse
The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit
The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit
The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 25 cm³:20 mL and extracted at 50°C for 72 hours. The test article extracts met the requirements of a USP Plastic Class VI.

Microscopic Examination of Implant Sites
The microscopic reaction of the test article was minimal as compared to the USP negative control plastic.

APPROVAL
Arizona E. Carter, BS, ALAT
Technical Reviewer

Date
05-01-18